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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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DEC 8 - 2000

Applicant's or agent's file reference 10738-17 PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/06580	International filing date *(day/month/year)* 25 MARCH 1999	Priority date *(day/month/year)* 31 MARCH 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant UNIVERSITY OF CINCINNATI		

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1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 9 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☒ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☒ Certain defects in the international application

   VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18 OCTOBER 1999	21 JUNE 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOYCE BRIDGERS PARALEGAL SPECIALIST DEVESH SRIVASTAVA, PH.D. CHEMICAL MATRIX Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/06580

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-43, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the claims:
pages 52-67, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the drawings:
pages 1-4, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

[X] the sequence listing part of the description:
pages 44-51, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[X] contained in the international application in printed form.

[X] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [X] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/06580

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

   [X] restricted the claims.

   [ ] paid additional fees.

   [ ] paid additional fees under protest.

   [ ] neither restricted nor paid additional fees.

2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   [ ] complied with.

   [X] not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   [ ] all parts.

   [X] the parts relating to claims Nos. 1-27.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/06580

V. Reasoned statement under Article 35(2) with regard t n velty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	3-27	YES
	Claims	1-2	NO
Inventive Step (IS)	Claims	3-27	YES
	Claims	1-2	NO
Industrial Applicability (IA)	Claims	1-27	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-2 lack novelty under PCT Article 33(2) as being anticipated by Rhone-Poulenc Rorer (FR 2 686 605)

Rhone-Poulenc Rorer teach apolipoproteins A-IV that are 376 amino acids in length (page 1, lines 6-7) that are useful for treatment of hypercholesterolnemias and atherosclerosis, wherein the latter condition, which as stated in the instant specification at page 2, line 11 to page 4, line 10, is related to lipid oxidation. Therefore, Rhone-Poulenc Rorer anticipate the claims.

Claims 3-27 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of treating [medical] conditions associated with lipid oxidation, specifically those conditions associated with atherosclerosis, by use of apolipoprotein A-IV compounds defined by SEQ ID NO:1-13.

Claims 1-27 meet the criteria set out in PCT Article 33(4) for industrial applicability.

---------- NEW CITATIONS ----------

NONE

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: there is no description for Figure 4 in the section Brief Description of the Figures.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-3 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not enabled as required under PCT Rule 5.1(a) for the reasons set forth in the following paragraph. Claims 1-3 encompass a method of treating conditions associated with lipid oxidation, specifically related to atherosclerosis, comprising use of apolipoprotein IV compounds (claim 1), their derivatives, analogs, homologs, fragments and mixtures thereof (claim 2) and which comprise a sequence of amino acids between 5 to 90 amino acids in length. However, the description only discloses the amino acid sequences of SEQ ID NO:1-13 as embodiments capable of this function. Further, the amino acid sequences of SEQ ID NO:1-13 range from 6 to 71 amino acids in length, not 5 to 90. Thus, the description doe not enable the full scope of the claims.

Claim 2 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): it is unclear what the derivatives, analogs, homologs, fragments and mixtures of apolipoprotein A-IV compounds are.

Supplemental B x
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:
The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): A61K 38/00; C07K 14/775 and US Cl.: 514/12, 13, 14, 15, 16; 530/324, 326, 327, 328, 329, 359

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
NONE

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:
As applicant was previously notified this International Preliminary Examining Authority has found plural inventions claimed in the International Application covered by the claims indicated below:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-27, drawn to a method of treating conditions associated with lipid oxidation.
Group II, claims 28-34, drawn to a method of preventing oxidation in a lipid-containing food.
Group III, claims 35-41, drawn to a method of preventing oxidation in a lipid-containing pharmaceutical.
Group IV, claims 42-62, drawn to a method of preventing oxidation using a cosmetic or dermatological composition and a cosmetic or dermatological composition.

and it considers that the International Application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated below:

The inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features are apolipoprotein A-IV compounds, which are known in the art, and each claimed method utilizing said compounds requires materially different steps. Specifically, Group I is drawn to treatment of medical conditions [in an animal] that requires consideration of methods of medical treatment related to lipid oxidation resulting in atherosclerosis. Group II is drawn to a method of preventing oxidation in lipid-containing food that requires consideration of lipid biology in plants and animals as well as food handling and storage considerations. Group III is drawn to a method of preventing oxidation in a lipid-containing pharmaceutical that requires consideration of pharmaceutical compositions, formulations and storage. Group IV is drawn to a method for preventing oxidation [of skin] using a cosmetic or dermatological composition and to a cosmetic or dermatological composition which requires consideration of dermatologic or cosmetic compositions as well as methodology of skin treatments that encompass the field of dermatology. Since each method recited above requires different considerations, each method would also encompass wholly different steps to carry out the invention(s). For these reasons, the inventions lack a single inventive concept under PCT Rule 13.1.